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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,072	07/17/2003	Kathryn E. Uhrich	01435.028US1	5968

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,072	UHRICH ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *8 and 16-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *December 22, 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/012/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, as well as Compound I and the absence of a biologically active molecule, in the reply filed on May 13, 2008 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner to examine both groups as well as all species. This is not found persuasive because not only do the different groups have different search and examination considerations which would present a burden on the examiner because it is not possible thorough and comprehensive examination of both the method and the device claims, which include sequences and other pieces that are not in part of the normal subject matter examined by the same art units. Additionally, the number of compounds encompassed by formulas I-XIII are in the thousands and would most certainly present a burden on the examiner as each structurally distinct compound would require its own search.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for films, does not reasonably provide enablement for any therapeutic device. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant claims "a therapeutic device for tissue regeneration comprising a biodegradable polymer" but does not specify what type of device is used, and thus the claim encompasses any therapeutic device to which a biodegradable polymer can be added such as a stent or a patch. Applicant has not shown how to make or use therapeutic devices other than films made of compressed polymer.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation necessary is high (1) due to the lack of direction provided to any other therapeutic device (2) and the lack of examples directed toward

any other therapeutic device (3). The nature of the invention is any therapeutic device (4) which is extremely broad and not all such devices are obvious how the polymer would be attached or contained in (5). The skill of those in the art is high (6) however the unpredictability of different compounds in various therapeutic devices can also be high (7) and the breadth of the claims is extremely large (8).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Erdmann et al. (Synthesis and degradation characteristics of salicylic acid-derived poly(anhydride-esters), cited on applicant's IDS).

In claim 1 applicant claims a therapeutic device comprising a biodegradable polymer to provide a sustained release of an anti-inflammatory compound to a tissue. Applicant has elected salicylic acid as the specific anti-inflammatory compound, and compound I as the biodegradable polymer, and thus claims 2-7, 9, and 12-15 read on a therapeutic device containing compound I (page 40 of specification). Erdmann et al.

teaches the exact same polymer (page 1942, scheme 1), and teaches that it degrades in the presence of water to produce salicylic acid (page 1942, scheme 1; and page 1941, column 2, paragraphs 3-4). They further teach the use of these polymers for site-specific drug targeting (page 1941, column 1, paragraph 1). Thus they teach a therapeutic device (the polymer itself) which comprises the exact same polymer as claimed and thus can treat the same tissues because it is the same composition. Thus Erdmann et al. anticipates claims 1-7, 9, and 12-15.

In claims 10 and 11 applicant claims that the tissue to be treated in claim 1 is neural tissue. Since the claims are drawn to a device, and the identical device is taught by Erdmann et al., the use or tissue it could treat does not carry patentable weight, as the same composition can be used for the same thing and the intended use does not affect this. Thus claims 10-11 are also anticipated by Erdmann et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erdmann et al. (Synthesis and degradation characteristics of salicylic acid-derived poly(anhydride-esters), cited on applicant's IDS).

In claim 1 applicant merely claims "a therapeutic device for tissue regeneration comprising a biodegradable polymer" and the device could be anything that can be used therapeutically, including just the polymer itself. It could also include other forms such as the polymer pressed into a film or a roll, implanted into a stent or even applied topically. Erdmann et al. teaches the same polymer, releasing the salicylic acid, as discussed above and it would have been obvious to one of ordinary skill in the art that the polymer could be used other conventional ways in which biodegradable polymers are known. Thus claims 1-7, and 9-15 are unpatentable over Erdmann et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614